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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,095	05/30/2006	Lawrence J. Putz	2074	9034

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,095	PUTZ, LAWRENCE J.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *26-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13, 15-17 and 19-25 (14 & 18 are omitted)* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt is acknowledged of the Response to Restriction/Election filed 01/26/10 and the Information Disclosure Statement (IDS) filed 03/27/06.

Applicant's election with traverse of Group I (claims 1-25) and Election of Species of emulsifier: (a) casein and Election of Species of class of oil: (a) vegetable oil in the reply filed on 26 January 2010 is acknowledged. The traversal is on the ground(s) that "The general inventive concept presented by Applicant is that of concealing a medication or supplement ('dosage') in a manner to facilitate oral administration to an animal and Applicant submits that the invention or group of inventions disclosed are so linked so as to form a single general inventive concept". This is not found persuasive with regards to the restriction between the groups (groups I-II) because Group I is drawn to an entirely different form that that of the Group II invention. Group I is drawn to a compound only whereas Group II is drawn to a product comprising a dosage of a compound AND a coating that substantially encloses the dosage form. Hence, the invention of Group II entails an encapsulated dosage form product. Group I, however, does not require the encapsulation means (i.e., coating) of the Group II invention and thus is structurally and functionally distinct from the Group II invention. Therefore, the groups entail different issues with respect to patentability and enablement. Art anticipating Group I would not anticipate, nor necessarily render obvious the invention of Group II. Furthermore, separate searches would be required in both patent- and non-patent databases and there is no expectation that the searches would be coextensive in scope. This creates an undue search burden upon the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's arguments drawn to the Election of Species requirement for category (1): election of emulsifier and category (2): election of class of oil has been considered and was found to be persuasive. Accordingly, the Election of Species requirement for categories 1 and 2 has been withdrawn.

Claims 26-38 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 01/26/10.

Claims 1-38 are pending in this action. Claims 26-38 have been withdrawn (non-elected invention). Claims 1-13, 15-17 and 19-25 have been examined in this action. Claims 1-13, 15-17 and 19-25 are rejected. (Claims 14 and 18 were omitted in the most recent claim set of 6/15/10 and thus, have not been examined on the merits) (see below).

Please Note: Claim 14, which has been omitted from the original submission, will retain its original numbering for the sake of examination purposes. Also note that there is no claim 18 in the most recent set of claims (filed 06/15/10). Claims 14 and 18 are absent in the rejections below as these claims have been omitted and limitations to these claims have not been presented by Applicant. Thus, claims 14 and 18 were not examined on the merits. The Examiner kindly requests that the claim numbering issue be corrected in Applicant's next response.

* * * * *

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

* * * * *

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 27 March 2006 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-6, 9 and 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Hiramoto *et al.* (hereinafter "Hiramoto") (U.S. Pat. Appln. Pub. No. 2006/0239939).

Hiramoto ('939) discloses deodorant compositions and products, such as oral care products, pet products, foods and animal feeds containing the deodorant compositions (see ¶s 0001, 0015, 0069). The deodorant compositions can contains flavors, fragrances, fillers, stabilizers, colorants, surfactants, antimicrobial agents (sodium benzoate, benzoic acid) and the like (¶s 0059-0063). The deodorant composition can be in various forms, including a dispersion or solution, made by the addition of a solvent, such as water (¶ 0065-0066). Deodorant compositions usable in pet products are further described at ¶ 0076-0077 and 0081.

The examples describe various embodiments of the invention. Example 8 at page 6 for instance, demonstrates a deodorant composition-containing mouth rinsing solution. The composition comprises ethyl alcohol, polyoxyethylene hydrogenated castor oil, sodium saccharin, glycerin, sodium benzoate and purified water. These ingredients directly read on the limitations and ingredients of instant claims 1 and 6, for the recitation of a compound containing: water, hydrogenated oil, emulsifier and preservative. Also see Example 14 at page 7. Sodium carboxymethylcellulose is disclosed at ¶ 0095. Corn starch is disclosed at ¶ 0099.

The instant claims are anticipated by Hiramoto.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13, 15-17 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel *et al.* (hereinafter "Patel") (U.S. Pat. No. 6,248,363).

Patel ('363) teaches pharmaceutical compositions and dosage forms including solid carriers for improved delivery of pharmaceutical active ingredients (see column 1, lines 5-12, col. 2, line 19 – col. 3, line 31 and Abstract). The active ingredients can be any compound or mixture of compounds having therapeutic value when administered to an animal, particularly to a mammal (col. 4, lines 35-56). The active ingredient can be, for example, a nutrient, cosmeceutical, diagnostic agent or nutritional agent (col. 4, lines 65-67). Suitable ingredients for use in the compositions include: (a) water (as solvent) (col. 40, lines 51-52); (b) hydrogenated vegetable oils (see for instance Tables 5, 19); (col. 39, lines 20-21) and fish oils (col. 35, lines 25-32); (c) emulsifiers, such as mono- and diacetylated monoglycerides (see for instance Table 9); (d) preservatives (i.e., sorbic acid) (col. 40, lines 47-50); (e) sweeteners (i.e., sorbitol) (col. 40, lines 53-56); (f) binders (i.e., starches) (col. 39, lines 30-42); (g) thickeners/viscosity modifiers (cellulosics) (col. 40, lines 57-59); (h) colorants (col. 40, lines 12-15); (i) flavorants (col. 40, lines 36-37) and (j) anti-adherents/anti-sticking agents, glidants and flow promoters such as Cabosil, Aerosil (fumed silicone dioxide), etc. (col. 39, lines 15-22). Additional additives disclosed include, for example, sodium carboxymethylcellulose (col. 41, line 5). The compositions are suitable for various uses (i.e., oral, topical, nasal, etc.) (col. 41, lines 29-54).

With respect to the instantly claimed amounts and/or ranges of the water, emulsifier, hydrogenated oil and viscosifier, while the instant amounts/ranges are not explicitly taught, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such

concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller,* 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Furthermore, while the strength (peel, tensile and compression strength) of the composition/compound is not disclosed, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable peel, tensile and compression strengths through the use of routine or manipulative experimentation, to obtain the best possible results, as these are variable parameters attainable within the art.

With regards to the limitation of a compound "adapted to conceal a medication/supplement when administered to an animal", the Examiner points out that this is a future-intended use limitation, which without structural limitation, does not accord patentable weight to the claims. The particular use of the compound (such as for concealment purposes or otherwise) denotes a future-use of the compound and thus does not impart patentability to the product (compound) being claimed.

The instant invention would have been *prima facie* obvious, given the teachings of Patel. Patel teaches pharmaceutical compositions and dosage forms for the delivery of active ingredients. The compositions comprise ingredients and elements such as those presently claimed and include: water, hydrogenated vegetable oils, fish oils, emulsifiers, preservatives, sweeteners, binders, thickeners/viscosity modifiers, anti-adherents/anti-sticking agents, glidants, flow promoters, colorants and flavorants. The active ingredients can comprise any compound(s) when administered to animals (i.e., mammals).

* * * * *

Claims 1-13, 15-17 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kutilek, III *et al.* (hereinafter "Kutilek") (U.S. Pat. No. 5,770,217).

Kutilek ('217) teaches a dietary or nutritional food supplement comprising herbs, herbal extracts, vitamins, minerals and amino acids (see Abstract); (col. 1, line 56 – col. 2, line 6). The supplement is particularly suitable for use in a method of treating human or animal subjects (col. 2, lines 7-35); (col. 3, lines 31-37). The dietary supplement comprises adjuvants or excipients such as, for example, binders (stearic acid), silicon dioxide (as a flow enhancer) and sodium carboxymethylcellulose. Also included are colorants, flavors (i.e., grape/cherry), diluents and the like. Corn starch and sweeteners can also be used (col. 7, line 15 – col. 8, line 2). The dietary supplement also includes the use of hydrogenated and partially hydrogenated vegetable oils, animal fats, light mineral oils, sodium benzoate (preservative), polyoxyethylene monostearate and sodium lauryl sulphate (emulsifier/surfactant) and the like (col. 8, lines 60-67). These ingredients may be used in amounts of 0% up to 1.5% dry weight of the total composition (col. 9, lines 1-4). Lecithin (emulsifier/surfactant) is disclosed at column 9, lines 20-24).

The Examples and Tables at columns 9-19 demonstrate various embodiments of the invention.

With respect to the instantly claimed amounts and/or ranges of the water, emulsifier, hydrogenated oil and viscosifier, while the instant amounts/ranges are not explicitly taught, the Examiner points out that, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

In re Aller, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Furthermore, while the strength (peel, tensile and compression strength) of the composition/compound is not disclosed, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable peel, tensile and compression strengths through the use of routine or manipulative experimentation, to obtain the best possible results, as these are variable parameters attainable within the art.

With regards to the limitation of a compound "adapted to conceal a medication/supplement when administered to an animal", the Examiner points out that this is a future-intended use limitation, which without structural limitation, does not accord patentable weight to the claims. The particular use of the compound (such as for concealment purposes or otherwise) denotes a future-use of the compound and thus does not impart patentability to the product (compound) being claimed.

The instant invention would have been *prima facie* obvious, given the teachings of Kutilek. Kutilek teaches a dietary supplement comprising a combination of herbs, vitamins, minerals, amino acids with hydrogenated vegetable oils, emulsifiers/surfactants, preservatives, sweeteners, binders, lubricants/anti-adherents, flow enhancers, colorants and flavorants. The supplement is particularly suitable for treating human or animal subjects. Thus, the instant invention would have been *prima facie* obvious over Kutilek.

* * * * *

Claims 1, 2, 4-13, 15-17, 19-22 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melrose *et al.* (hereinafter "Melrose") (U.S. Pat. No. 7,629,002).

Melrose ('002) teaches antimicrobial compositions and methods for using the same (see Abstract). The invention also provides an animal feed composition comprising the antimicrobial and a feedstuff (col. 7, lines 64-67). The antimicrobial compositions are particularly preferred for use in the treatment of animals (i.e., dogs, cats, etc.) (column 5, lines 53-65). The antimicrobial can be incorporated into animal feed or water (col. 6, line 62 – col. 7, line 21). Suitable ingredients for use in the composition include oils (col. 8, lines 7-14), binders, sweeteners, disintegrants, flavorings, preservatives, lubricants and the like (col. 8, lines 15-18). Specific ingredients disclosed include corn starch, mannitol, dicalcium phosphate, flavorings (cherry, etc.), preservatives such as methyl parabens, ascorbic acid, sodium benzoate, anti-adherents (i.e., talc), glyceryl monostearate and distearate, emulsifying agents, sodium carboxymethylcellulose and the like (col. 8, lines 19-52).

The Examples and Tables demonstrate various embodiments of the invention.

With respect to the instantly claimed amounts and/or ranges of the water, emulsifier, hydrogenated oil and viscosifier, while the instant amounts/ranges are not explicitly taught, the Examiner points out that, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller,* 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Furthermore, while the strength (peel, tensile and compression strength) of the composition/compound is not disclosed, it is the

position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable peel, tensile and compression strengths through the use of routine or manipulative experimentation, to obtain the best possible results, as these are variable parameters attainable within the art.

With regards to the limitation of a compound "adapted to conceal a medication/supplement when administered to an animal", the Examiner points out that this is a future-intended use limitation, which without structural limitation, does not accord patentable weight to the claims. The particular use of the compound (such as for concealment purposes or otherwise) denotes a future-use of the compound and thus does not impart patentability to the product (compound) being claimed.

The instant invention would have been *prima facie* obvious, given the teachings of Melrose. Melrose teaches antimicrobial compositions comprising oils, binders, sweeteners, disintegrants, flavorings, preservatives, lubricants, emulsifying agents and the like. The antimicrobial compositions are particularly preferred for use in the treatment of animals (i.e., dogs, cats, etc.). Thus, the instant invention would have been *prima facie* obvious over Melrose.

* * * * *

Claims 1, 2, 4-13, 15-17, 19-22 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satoh *et al.* (hereinafter "Satoh") (U.S. Pat. No. 5,244,669).

Satoh ('669) teaches feed additives for ruminants for the purpose of supplementing nutrients and/or preventing diseases of livestock (see column 1, line 5 – col. 2, line 29). The compositions comprise proteins, oils and fats, fatty acids and the like (col. 3, lines 5-40);

ingredients such as binders, disintegrants (sodium carboxymethylcellulose), hydrogenated vegetable oils, emulsifiers, such as casein and disodium phosphate, preservatives, sweeteners (i.e., mannitol), anti-adherents (i.e., talc), corn starch and the like are also disclosed. See for instance column 3, lines 48-68; col. 6, line 49 – col. 7, line 3 and Examples.

With respect to the instantly claimed amounts and/or ranges of the water, emulsifier, hydrogenated oil and viscosifier, while the instant amounts/ranges are not explicitly taught, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller,* 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Furthermore, while the strength (peel, tensile and compression strength) of the composition/compound is not disclosed, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable peel, tensile and compression strengths through the use of routine or manipulative experimentation, to obtain the best possible results, as these are variable parameters attainable within the art.

With regards to the limitation of a compound "adapted to conceal a medication/supplement when administered to an animal", the Examiner points out that this is a future-intended use limitation, which without structural limitation, does not accord patentable weight to the claims. The particular use of the compound (such as for concealment purposes or otherwise) denotes a future-use of the compound and thus does not impart patentability to the

product (compound) being claimed. Nonetheless, the compositions of Satoh are used in animal products, such as animal feed.

The instant invention would have been *prima facie* obvious, given the teachings of Satoh. Satoh teaches feed additives for ruminants wherein the additives comprise ingredients and elements such as those presently claimed and include: water, hydrogenated vegetable oils, animal oils, emulsifiers, preservatives, sweeteners, binders and the like.

* * * * *

Pertinent Art

Prior Art cited of interest by the Examiner:

U.S. Patent No. 5,439,924 (Miller) (08-08-1995)

* * * * *

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615

hns

August 16, 2010